milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 6.25 to 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(11) *For products containing pyrilamine maleate identified in § 341.12(k).* Adults and children 12 years of age and over: oral dosage is 25 to 50 milligrams every 6 to 8 hours, not to exceed 200 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 to 25 milligrams every 6 to 8 hours, not to exceed 100 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(12) *For products containing thonzylamine hydrochloride identified in § 341.12(l).* Adults and children 12 years of age and over: oral dosage is 50 to 100 milligrams every 4 to 6 hours, not to exceed 600 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 25 to 50 milligrams every 4 to 6 hours, not to exceed 300 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(13) *For products containing triprolidine hydrochloride identified in § 341.12(m).* Adults and children 12 years of age and over: oral dosage is 2.5 milligrams every 4 to 6 hours, not to exceed 10 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 1.25 milligrams every 4 to 6 hours, not to exceed 5 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

[57 FR 58374, Dec. 9, 1992, as amended at 59 FR 4218, Jan. 28, 1994; 67 FR 72559, Dec. 6, 2002]

### § 341.74 Labeling of antitussive drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a ''cough suppressant'' or an ''antitussive (cough suppressant).''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) ''Temporarily'' (select one of the following: ''alleviates,'' ''calms,'' ''controls,'' ''decreases,'' ''quiets,'' ''reduces,'' ''relieves,'' or ''suppresses'') ''cough due to'' (select one of the following: ''minor bronchial irritation'' or ''minor throat and bronchial irritation'') (select one of the following: ''as may occur with,'' ''associated with,'' or ''occurring with'') (select one of the following: ''A cold'' or ''the common cold'') ''or inhaled irritants.''

(2) ''Temporarily'' (select one of the following: ''alleviates,'' ''calms,'' ''controls,'' ''decreases,'' ''quiets,'' ''reduces,'' ''relieves,'' or ''suppresses'') ''cough'' (select one of the following: ''as may occur with,'' ''associated with,'' or ''occurring with'') (select one of the following: ''A cold,'' ''the common cold,'' or ''inhaled irritants'').

(3) In addition to the required information identified in paragraphs (b) (1) and (2) of this section, the labeling of the product may contain any (one or more) of the following statements:

(i) ''Cough suppressant which temporarily'' (select one of the following: ''Alleviates,'' ''controls,'' ''decreases,'' ''reduces,'' ''relieves,'' or ''suppresses'') ''the impulse to cough.''

(ii) ''Temporarily helps you cough less.''

(iii) ''Temporarily helps to'' (select one of the following: ''Alleviate,'' ''control,'' ''decrease,'' ''reduce,'' ''relieve,'' or ''suppress'') ''the cough reflex that causes coughing.''

(iv) ''Temporarily'' (select one of the following: ''Alleviates,'' ''controls,'' ''decreases,'' ''reduces,'' ''relieves,'' or

''suppresses'') ''the intensity of coughing.''

(v) (Select one of the following: ''Alleviates,'' ''Controls,'' ''Decreases,'' ''Reduces,'' ''Relieves,'' or ''Suppresses'') (select one of the following: ''Cough,'' ''the impulse to cough,'' or ''your cough'') ''to help you'' (select one of the following: ''Get to sleep,'' ''sleep,'' or ''rest'').

(vi) *For products containing chlophedianol hydrochloride, codeine ingredients, dextromethorphan, or dextromethorphan hydrobromide identified in § 341.14(a) (1), (2), (3), and (4).* ''Calms the cough control center and relieves coughing.''

(vii) *For products containing chlophedianol hydrochloride, dextromethorphan, dextromethorphan hydrobromide, camphor, or menthol identified in § 341.14(a) (1), (3), (4) and (b) (1) and (2).* (*a*) ''Nonnarcotic cough suppressant for the temporary'' (select one of the following: ''alleviation,'' ''control,'' ''decrease,'' ''reduction,'' ''relief,'' or ''suppression'') ''of cough.''

(*b*) (Select one of the following: ''Alleviates,'' ''Controls,'' ''Decreases,'' ''Reduces,'' ''Relieves,'' or ''Suppresses'') ''cough impulses without narcotics.''

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) *For oral and topical antitussives.* ''A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.''

(2) *For oral and topical antitussives labeled for adults or for adults and children under 12 years of age.* ''Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.''

(3) *For oral and topical antitussives labeled only for children under 12 years of age.* ''Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.''

(4) *Oral antitussives*—(i) *For products containing codeine ingredients identified in § 341.14(a)(2).* ''May cause or aggravate constipation.''

(ii) *For products containing codeine ingredients identified in § 341.14(a)(2) when labeled only for adults.* ''Do not take this product if you have a chronic pulmonary disease or shortness of breath unless directed by a doctor.''

(iii) *For products containing codeine ingredients identified in § 341.14(a)(2) when labeled only for children under 12 years of age.* ''Do not give this product to children who have a chronic pulmonary disease, shortness of breath, or who are taking other drugs unless directed by a doctor.''

(iv) *For products containing codeine ingredients identified in § 341.14(a)(2) when labeled for use in adults and children under 12 years of age.* ''Adults and children who have a chronic pulmonary disease or shortness of breath, or children who are taking other drugs, should not take this product unless directed by a doctor.''

(v) *For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14 (a)(3) and (a)(4) when labeled for adults or for adults and children under 12 years of age. Drug interaction precaution.* ''Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.''

(vi) *For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14 (a)(3) and (a)(4) when labeled only for children under 12 years of age. Drug interaction precaution.* ''Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.''

(vii) *For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified*

*in § 341.14 (a)(5) and (a)(6).* ''May cause excitability especially in children.''

(viii) *For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.14 (a)(5) and (a)(6) when labeled only for children under 12 years of age*—(A) ''Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, without first consulting the child's doctor.''

(B) ''May cause marked drowsiness. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child's doctor.''

(C) ''Do not use [bullet][1] with any other product containing diphenhydramine, even one used on skin''.

(ix) *For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.14 (a)(5) and (a)(6) when labeled for use in adults and children under 12 years of age*—(A) ''Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland.''

(B) ''May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.''

(C) ''Do not use [bullet] with any other product containing diphenhydramine, even one used on skin''.

(5) *Topical antitussives*—(i) *For products containing camphor or menthol identified in § 341.14 (b) (1) and (2) in a suitable ointment vehicle.* ''For external use only. Do not take by mouth or place in nostrils.''

(ii) *For products containing camphor or menthol identified in § 341.14(b) (1) and (2) for steam inhalation use.* ''For steam inhalation only. Do not take by mouth.''

(iii) *For any product containing camphor or menthol in a suitable ointment vehicle or for steam inhalation use and meets the definition of one of the signal words (''extremely flammable,'' ''flammable,'' ''combustible'') as described in 16 CFR 1500.3(b)(10).* The labeling contains the appropriate flammability signal word(s) followed by a colon and the statement ''Keep away from fire or flame.''

(iv) *For any product containing camphor or menthol in a suitable ointment vehicle and that does not contain a flammability signal word as described in 16 CFR 1500.3(b)(10).* ''When using this product, do not [bullet][1] heat [bullet] microwave [bullet] add to hot water or any container where heating water. May cause splattering and result in burns.'' [Information highlighted in bold type.]

(v) *For any product containing camphor or menthol in a suitable ointment vehicle and that contains a flammability signal word as described in 16 CFR 1500.3(b)(10).* ''When using this product, do not [bullet] heat [bullet] microwave [bullet] use near an open flame [bullet] add to hot water or any container where heating water. May cause splattering and result in burns.'' [Information highlighted in bold type.]

(vi) *For any product containing camphor or menthol for steam inhalation use.* ''When using this product, do not [bullet] heat [bullet] microwave [bullet] use near an open flame [bullet] add to hot water or any container where heating water except when adding to cold water only in a hot steam vaporizer. May cause splattering and result in burns.'' [Information highlighted in bold type.]

(vii) *For any product formulated in a volatile vehicle.* The labeling contains the following statement under the heading ''Other information'': ''Close container tightly and store at room temperature away from heat.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

[1] See § 201.66(b)(4) of this chapter for definition of bullet symbol.

[1] For a definition of the term ''bullet,'' see § 201.66(b)(4) of this chapter.

(1) *Oral antitussives*—(i) *For products containing chlophedianol hydrochloride identified in § 341.14(a)(1).* Adults and children 12 years of age and over: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 100 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 milligrams every 6 to 8 hours, not to exceed 50 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.

(ii) *For products containing codeine ingredients identified in § 341.14(a)(2).* Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 to 6 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 to 6 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

(iii) *For products containing dextromethorphan or dextromethorphan hydrobromide identified in § 341.14(a) (3) and (4).* The dosage is equivalent to dextromethorphan hydrobromide. Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 hours or 30 milligrams every 6 to 8 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 hours or 15 milligrams every 6 to 8 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: Oral dosage is 2.5 to 5 milligrams every 4 hours or 7.5 milligrams every 6 to 8 hours, not to exceed 30 milligrams in 24 hours, or as directed by a doctor. Children under 2 years of age: Consult a doctor.

(iv) *For products containing diphenhydramine citrate identified in § 341.14(a)(5).* Adults and children 12 years of age and over: oral dosage is 38 milligrams every 4 hours, not to exceed 228 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 19 milligrams every 4 hours, not to exceed 114 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(v) *For products containing diphenhydramine hydrochloride identified in § 341.14(a)(6).* Adults and children 12 years of age and over: oral dosage is 25 milligrams every 4 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 milligrams every 4 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(2) *Topical antitussives*—(i) *For products containing camphor identified in § 341.14(b)(1) in a suitable ointment vehicle.* The product contains 4.7 to 5.3 percent camphor. ''[bullet] see important warnings under 'When using this product' [appears as the first statement under the heading ''Directions'' and is highlighted in bold type] [bullet] adults and children 2 years and older: [bullet] rub on the throat and chest in a thick layer [bullet] cover with a warm, dry cloth if desired [bullet] clothing should be loose about throat and chest to help vapors reach the nose and mouth [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(ii) *For products containing menthol identified in § 341.14(b)(2) in a suitable ointment vehicle.* The product contains 2.6 to 2.8 percent menthol. ''[bullet] see important warnings under 'When using this product' '' [appears as the first statement under the heading ''Directions'' and is highlighted in bold type] [bullet] adults and children 2 years and older: [bullet] rub on the throat and chest in a thick layer [bullet] cover with a warm, dry cloth if desired [bullet] clothing should be loose about throat and chest to help vapors reach the nose and mouth [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(iii) *For products containing menthol identified in § 341.14(b)(2) in a lozenge.* The product contains 5 to 10 milligrams menthol. Adults and children 2 to under 12 years of age: Allow lozenge

to dissolve slowly in the mouth. May be repeated every hour as needed or as directed by a doctor. Children under 2 years of age: Consult a doctor.

(iv) *For products containing camphor identified in § 341.14(b)(1) for steam inhalation use.* The product contains 6.2 percent camphor. ''[bullet] see important warnings under 'When using this product' '' [appears as the first statement under the heading ''Directions'' and is highlighted in bold type] [bullet] adults and children 2 years and older: (select one of the following, as appropriate: *For products formulated to be added directly to cold water inside a hot steam vaporizer.* [bullet] use 1 tablespoonful of solution for each quart of water or 1½ teaspoonsful of solution for each pint of water [bullet] add solution directly to cold water only in a hot steam vaporizer [bullet] follow manufacturer's directions for using vaporizer or *For products formulated to be placed in the medication chamber of a hot steam vaporizer.* [bullet] place water in the vaporizer and follow manufacturer's directions for using vaporizer [bullet] place solution in the medication chamber only) [bullet] breathe in the medicated vapors [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(v) *For products containing menthol identified in § 341.14(b)(2) for steam inhalation use.* The product contains 3.2 percent menthol. ''[bullet] see important warnings under 'When using this product' ''[appears as the first statement under the heading ''Directions'' and is highlighted in bold type] [bullet] adults and children 2 years and older: (select one of the following, as appropriate: *For products formulated to be added directly to cold water inside a hot steam vaporizer.* [bullet] use 1 tablespoonful of solution for each quart of water or 1½ teaspoonsful of solution for each pint of water [bullet] add solution directly to cold water only in a hot steam vaporizer [bullet] follow manufacturer's directions for using vaporizer or *For products formulated to be placed in the medication chamber of a hot steam vaporizer.* [bullet] place water in the vaporizer and follow manufacturer's directions for using vaporizer [bullet] place solution in the medication chamber only) [bullet] breathe in the medicated vapors [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

(f) *Exemption from the general accidental overdose warning.* The labeling for antitussive drug products containing the active ingredient identified in § 341.14(b)(2) marketed in accordance with § 341.74(d)(2)(iii) is exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement ''In case of accidental overdose, seek professional assistance or contact a poison control center immediately.'' The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, ''Keep this and all drugs out of the reach of children.''

[52 FR 30055, Aug. 12, 1987; 52 FR 35610, Sept. 22, 1987; 53 FR 35809, Sept. 15, 1988; 55 FR 27808, July 6, 1990; 55 FR 40383, Oct. 3, 1990; 58 FR 54236, Oct. 20, 1993; 59 FR 29174, June 3, 1994; 59 FR 36051, July 15, 1994; 64 FR 13295, Mar. 17, 1999; 65 FR 8, Jan. 3, 2000; 65 FR 46867, Aug. 1, 2000; 67 FR 72559, Dec. 6, 2002]

### § 341.76 Labeling of bronchodilator drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a ''bronchodilator.''

(b) *Indication.* The labeling of the product states the following under the heading ''Use'': ''for temporary relief of mild symptoms of intermittent asthma: [bullet][1] wheezing [bullet] tightness of chest [bullet] shortness of breath''. Other truthful and nonmisleading statements, describing only the indication for use that has been established and listed in this paragraph (b) may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act relating to misbranding and the prohibition in section 301(d) of the Federal Food, Drug, and Cosmetic Act against

[1] See § 201.66(b)(4) of this chapter for the definition of ''bullet.''